

2180 Calumet Street, Clearwater, Fl 33765

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June 23, 2005

Division of Compliance and Enforcement/ONPLDS Center for Food Safety and Applied Nutrition Food and Drug Administration HFS-810 200 C Street, SW Washington, DC 20204

Dear Sirs,

In compliance with Section 6 of the Dietary Supplement Health and Education Act (DSHEA) and Rule 21 C.F.R. 101.93, notice is hereby given in duplicate that Nulab, Inc., located at 2180 Calumet Street, Clearwater, Florida 33765, has marketed a dietary supplement under the Nutrina brand bearing the following statements on the label:

GOOD NIGHT NATURALLY: (1) "This product contains natural ingredients that help promote sleep. Melatonin, a hormone produced by the pineal gland at night, can increase sleep efficiency and total sleep time. and help you fall asleep faster. 5-HTP, produced by extraction from seeds of the African Griffonia plant, can improve sleep quality. A combination of extracts from Valerian roots and Lemon balm leaves has also shown to enhance the quality of sleep." (2) "Reduces time to fall asleep. Increases sleep quality."

The undersigned certifies that the information contained in this notice is complete and accurate and that Nulab, Inc. has substantiation that these structure/function claims are truthful and not misleading.

Sincerely,

Marisol/Defino B. S. Biochemistry

**Quality Control Director** 

2005-4513 WXM5